

National Kidney Cancer Association

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Ms. Theresa A. Toigo
Associate Commissioner for Special Health Issues
Food & Drug Administration #949
5600 Fishers Lane, Parklawn HF12
Rockville, MD 20857

Dear Terry:

I am writing to express the position of the National Kidney Cancer Association with respect to Section 113 of the Food and Drug Administration Modernization Act. We believe that patients in search of clinical trial information will need the following minimal data set to retrieve the information needed to pursue the clinical trial:

- Name of the entity submitting the information
- Name(s) of institutions participating
- Eligibility requirements
- Number of patients sought
- Number of patient slots still open
- Non-technical description of protocol
- Date trial opened
- Telephone number where information requests should be submitted

I also want to take this opportunity to mention an area of increasing concern to us, namely the possible failure by some individuals involved in the clinical trial process to divulge conflicts of interest.

Sincerely,



Carl F. Dixon
President & Executive Director

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